IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent application of	)	Examiner: C. R. Lea
BAJAJ et al.	)	Art Unit: 1619
Serial No. 10/574,666	)	
Filed: April 4, 2006	)	Atty. Dkt. No.: 125139.0101
For: A NOVEL DRUG DELIVERY SYSTEM FOR PROTON PUMP INHIBITOR AND PROCESS THEREOF	)	

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner of Patents
P.O. Box 1540
Alexandria, VA 22313-1450

Sir:

In response to the Office Actions dated September 15, 2009, the undersigned declares as follows:

1. I, Bharat Babulal Shah, a citizen of India, residing at the below-referenced address, am an inventor of the above-identified patent application. I am a quality assurance general manager at Lyka Labs Limited. I received my Batchelor of Pharmacy from Gujarat University and have over thirty (30) years of experience in pharmaceutical analysis, including quality and reliability testing, data analysis, and GMP/GLP monitoring.

2. I have read and understood Doen et al. (US 2003/0191157). The data described herein was prepared in order to demonstrate the unexpected and superiority stability of the composition of the instant invention when compared to that disclosed by Doen et al., the closest cited prior art reference.

3. The data presented below was obtained by preparing two compositions, each containing 20 mg of rabeprazole sodium and other ingredients claimed by the present invention, except that one composition contains rabeprazole to alkaline compound in a ratio of 1:0.359 (composition A), while the other composition contains a ratio of rabeprazole to alkaline compound of 1:1 (composition B). The stability of compositions A and B in reconstituted solutions are presented in TABLE 1.

TABLE 1								
	Description		**pH**		**Clarity of solution**		**Amount of rabeprazole from assay (% of initial amount)**	
	A	B	A	B	A	B	A	B
Initial	Clear colorless solution	Clear colorless solution	10.11	10.49	Clear and free of particulates	Clear and free of particulates	20.18mg (100.9%)	19.52mg (97.6%)
After 1 hour	Clear colorless solution	Clear colorless solution	9.97	10.09	Clear and free of particulates	Clear and free of particulates	19.71mg (98.6%)	18.20mg (91.0%)
Desired specification	Clear colorless to pale yellow		9.0-11.0		Clear and free of particulates		90.0-110.0%	

A=composition A; B=composition B

4. In my opinion, the data shows that composition A (using the rabeprazole to alkaline compound ratio claimed by the present invention) unexpectedly outperforms the composition B (using the rabeprazole to alkaline compound ratio disclosed in Doen et al.), by significantly improve stability. One hour after reconstitution, only 91% of rabeprazole remains in composition B, while in composition A, 97.6% remains. Composition B is very near the bottom of the specified range (close to failing to meet specification). It is clear, thus, that by changing that ratio in accordance with the present invention, it is possible to significantly improve the stability of rabeprazole. That improvement is significantly and unexpected from the disclosure of the prior art.

5. The undersigned hereby declares that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: 15/12/09

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